

### REMARKS

Claims 1-5, 7-17 and 19-37 are currently pending in this application. Claims 24-37 stand withdrawn, and claims 1-5, 7-17, 19-23 stand rejected on various grounds. In the Office Action dated January 27, 2009, the Examiner took the following actions:

- 1) Rejected claims 1-3, 5, 7, and 9 under 35 U.S.C. § 103(a) as being unpatentable over Morita (U.S. Patent No. 5,730,753, "Morita") in view of Abulhaj et al. (U.S. Patent No. 6,852,119, "Abulhaj");
- 2) Rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Morita in view of Abulhaj and further in view of Bajaj et al. (U.S. Patent No. 6,056,765, "Bajaj");
- 3) Rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Morita in view of Abulhaj and further in view of Duchon et al. (U.S. Patent No. 5,964,718, "Duchon");
- 4) Rejected claims 10-12 under 35 U.S.C. § 102(b) as being anticipated by Hofert.
- 5) Rejected claims 13-15, 17, 19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over Hofert et al. (U.S. Patent No. 4,203,446, "Hofert") in view of Morita and further in view of Abulhaj;

- 6) Rejected claim 16<sup>1</sup> under 35 U.S.C. § 103(a) as being unpatentable over Hofert in view of Morita and Abulhaj and further in view of Bajaj;
- 7) Rejected claim 20<sup>2</sup> under 35 U.S.C. § 103(a) as being unpatentable over Hofert in view of Morita and Abulhaj and further in view of Duchon.

By this response, Applicants propose to amend claims 1, 3, 10, 13, and 15; and cancel claims 2, 4, 14 and 16 without prejudice. Of the claims under examination, claims 1, 10, and 13 are independent.

Applicants respectfully request reconsideration of the pending claims for at least the reasons that follow.

**I. Rejection of claims 1-5 and 7-9 under 35 U.S.C. § 103(a)- Morita as Primary Reference**

The Examiner rejected claims 1-3, 5, 7 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Morita in view of Abulhaj; claim 4 is rejected as being unpatentable over Morita in view of Abulhaj and further in view of Bajaj; and claim 8 is rejected as being unpatentable over Morita in view of Abulhaj and further in view of Duchon.

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<sup>1</sup> Applicants submit that there appears to be a typographical error in the Office Action. It looks as if the Examiner intended to reject claim 16, and not claim 6, under 35 U.S.C. § 103(a) as being unpatentable over Hofert in view of Morita and Abulhaj and further in view of Bajaj. Applicants respectfully request that the Examiner correct this typographical error in the next communication.

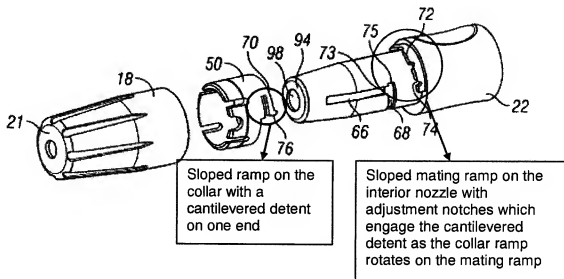
<sup>2</sup> Applicants submit that there appears to be a typographical error in the Office Action. It looks as if the Examiner intended to reject claim 20, and not claim 6, under 35 U.S.C. § 103(a) as being unpatentable over Hofert in view of Morita and Abulhaj and further in view of Duchon. Applicants respectfully request that the Examiner correct this typographical error in the next communication.

Applicants respectfully traverse the rejection of these claims for at least the following reasons.

With regard to independent claim 1, the Examiner asserts that Morita teaches each and every limitation of the claimed invention, except that "the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends", for which the Examiner relies on Abulhaj (See Office Action at p. 5).

Applicants respectfully traverse this rejection. Without acquiescing to the propriety of the Examiner's rejection, Applicants amend independent claim 1 to include the limitations "the interior nozzle comprising ....a sloped mating ramp comprising a plurality of adjustment notches" and "the collar further comprises a sloped collar ramp with a cantilevered detent on one end, wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation", the subject matter of which was previously stated in dependent claim 3. Applicants respectfully submit that neither Morita nor Abulhaj teach, disclose or suggest at least the above mentioned limitations of claim 1 as currently amended.

Fig. 9 of the present application, represent below, illustrates the sloped mating ramp 72 with adjustment notches 74 on the interior nozzle 22, and the sloped collar 70 with a cantilevered detent 76 on the collar 50.



In the outstanding Office Action, the Examiner asserts (with regard to dependent claim 3) that Morita discloses a protruding portion 53 on the adjustment element 5. The Examiner equates the protruding portion 53 to the detent, and the part that contains the protruding portion to the sloped collar ramp, as recited in independent claim 1. See Office Action at p. 7. Applicants respectfully disagree with the Examiner, and submit that the protruding portion 53 is simply present as a thread on the interior surface of the adjustment element 5, which is configured to engage the thread portion 17 of the cap element 3 through a screw engagement mechanism. First and foremost, the protruding portion 53 of Morita is not configured as a cantilevered detent. Second, independent claim 1 recites that the detent is on end of the sloped collar ramp. Whereas, the

protruding portion 53 of Morita extends throughout the thread portion of the adjustment element 5, as would be expected in any screw thread mechanism. Third, independent claim 1 recites that "the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation". The Examiner equates the interior nozzle mating ramp to the thread portion 17 of Morita, and the adjustment notches to the protruding portions sticking out between the thread grooves 47. *Id.* However, a notch by definition means an "indentation" (definition from Merriam-Webster Online Dictionary attached), and therefore, the protruding portions of the threading cannot be accurately compared to the adjustment notches of the present application.

Furthermore, Morita discloses that the protruding portion 53 is placed into the thread groove 47 of the thread portion 17.

At least one of the peripheral flap portion 21 of the adjusting element 5 comprises another protruding portion 53 as a thread portion on its inside. The thread portion 53 is so constructed that it is engaged with the thread portion 17 of the cap element 3 through the screw engagement mechanism, and thus the protruding portion 53 is present as a thread which is placed into the thread groove 47 of the thread portion 17.

Morita, col. 12, l. 60-67 (emphasis added)

The Examiner had previously asserted that the thread groove 47 and the protruding portion 53 of Morita are equivalent to the ramped groove and collar pin, respectively, as recited in amended claim 1. *Id.* at p. 5. Thus, the Examiner is considering the protruding portion 53 of Morita to be equivalent to both the collar pin and the detent of the present application, and the thread groove 47 of Morita to be

equivalent to both the ramped groove and the mating ramp of the interior nozzle. Applicants respectfully submit that the collar pin, the detent on the collar ramp, the ramped groove and mating ramp are all separate and independent elements of the claimed invention, as clearly shown in Fig. 9. Thus, the Examiner has failed to show that each and every element of independent claim 1 is taught, disclosed or suggested by Morita.

Additionally, Abulhaj does not cure these deficiencies of Morita. Nowhere does Abulhaj teach, disclose or suggest a collar having a sloped ramp and a cantilevered detent, which rotate on a sloped mating ramp on the interior nozzle, and wherein the mating ramp comprises adjustment notches.

Therefore, it is respectfully submitted that Morita and Abulhaj, either alone or in combination, fail to disclose or suggest each and every element of independent claim 1. Applicants, therefore, request that the rejection of claim 1 under 35 U.S.C § 103(a) be withdrawn. Claims 3, 5, 7 and 9 depend from independent claim 1, and therefore, are patentable over Morita and Abulhaj for at least the same reasons as claim 1.

With regard to claim 8, the Examiner relies on Duchon and alleges that "Duchon discloses that the contact surface (48) is concave..." (*Id.* at page 9). Such teachings, even if present in Duchon, which Applicants do not concede, fail to cure the deficiencies of Morita, as discussed earlier in this paper. Accordingly, claim 8 is patentable at least due to its dependence from independent claim 1.

By this response, Applicant proposes to cancel claims 2 and 4, thereby, mooted the rejection of these claims.

**II. Rejection of claims 10-12 under 35 U.S.C § 102(b)**

Claims 10-12 are rejected under 35 U.S.C § 102(b) as being anticipated by Hofert. Applicants respectfully traverse this rejection. In order to properly establish that Hofert anticipates Applicants' claimed invention under 35 U.S.C. § 102, each and every element of each of the claims in issue must be found, either expressly described or under principles of inherency, in that single reference. Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). In the present case, Hofert fails to disclose each and every element of independent claim 10 as described below.

Applicants assert that Hofert fails to disclose or suggest at least the limitations "a lancet holder comprising one or more retaining features and one or more spring surfaces at the distal end and one or more lancet holding features at the proximal end", "the rearward body engaging the retainer externally around the periphery of the retainer" and "the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring".

In the outstanding Office Action, the Examiner equates the blade guide 16 of Hofert to the lancet holder recited in claim 10. Further, the Examiner equates the one or more retaining features and the one or more spring surfaces, as recited in claim 10, to the collar 14 and the outer surface of the blade guide 16 of Hofert, respectively. However, claim 10, as amended, clearly recites that the one or more retaining features and the one or more spring surfaces are present on the distal end of the lancet holder.

and lancet holding features are present on the proximal end, as clearly shown in Fig. 4 and Fig. 5 of the present applicant. In contrast, Hofert discloses that the retaining features (collar 14) is present on the proximal end of the lancing device, and the spring surfaces (outer surface of blade guide 16) extend through out the lancet holder. In fact, Applicants assert that the collar 14 of Hofert comprises the lancet holding features at the proximal end of the device, as illustrated in Fig. 1 of Hofert. Hofert clearly fails to disclose any retaining features at the distal end of the lancet holder 10. Figs. 4 and 5 of the present application, and Fig. 1 of Hofert are depicted herein for ease of comparison. Thus, Hofert fails to disclose at least the limitation "a lancet holder comprising one or more retaining features and one or more spring surfaces at the distal end and one or more lancet holding features at the proximal end"

Claim 10, as amended, also recites that "the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring". That is, the internal compression spring 32 engages the lancet holder 34 within the interior tube 26 (as shown in Fig. 4), and the external compression spring 44 engages the lancet holder 34 near the retaining features 36 (as shown in Fig. 5). In the outstanding Office Action, the Examiner suggests that the striker spring 36 of Hofert is equivalent to the internal compression of the present application, the restoring spring 20 is equivalent to the external compression spring, and the blade guide 16 is equivalent to the lancet holder. See Office Action at p. 3. However, the spring 36 does not engage the blade guide 16 at all, as clearly demonstrated in Fig. 1 of Hofert. Thus, the Examiner has failed to show that Hofert discloses or suggests the above-mentioned limitation.



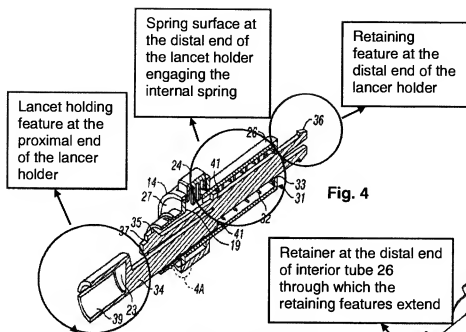


Fig. 4

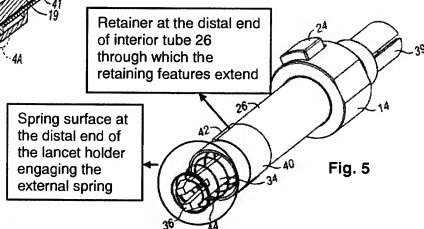


Fig. 5

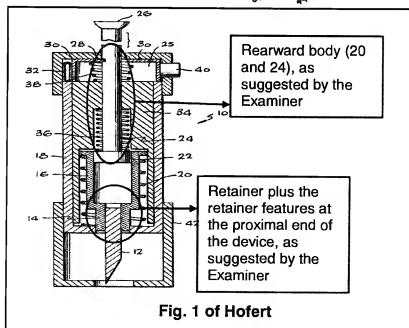


Fig. 1 of Hofert

In the outstanding Office Action, the Examiner is also referring to the collar 14 of Hofert as both the retainer and retaining features. *Id.* Applicants respectfully submit that the retaining features and the retainer of the present application as completely separate elements. As clearly recited in independent claim 10, the retaining features are present at the distal end of the lancet holder, and the retainer is present at the distal end of the internal tube. Thus, the Examiner has clearly failed to show that each and every element of independent claim 10 is taught, disclosed or suggested by Hofert.

Additionally, the Examiner equates the rearward body, as recited in claim 10, to the combination of the striker shaft 24 and striker plate 22. As shown in Fig. 1 of Hofert, the striker shaft 24 and striker plate 22 are positioned within mass 34, which the Examiner equates to the interior tube of the present application. *See* Office Action at p. 2. However, claim 10 recites that the rearward body is positioned exterior to the interior tube 26. Thus, the Examiner has again failed to show that the limitation "a rearward body, the rearward body engaging the retainer and positioned externally around the periphery of the interior tube", as recited in amended claim 10, is disclosed or suggested by Hofert.

In conclusion, Applicants respectfully submit that the Examiner has failed to show that each and every limitation of independent claim 10 is either expressly or inherently described in Hofert. Claim 10, therefore, is not anticipated by Hofert. Claims 11 and 12 depend from claim 10, and therefore, are allowable for at least the same reasons as claim 10.

**III. Rejection of claims 13-17 and 19-23 under 135 U.S.C. § 103(a)- Hofert as Primary Reference**

The Examiner rejected claims 13-15, 17, 19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over Hofert in view of Morita and further in view of Abulhaj.

The Examiner asserts that Hofert in view of Morita teaches all the limitations of claim 13, except that "the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends", for which the Examiner relies on Abulhaj. Applicants respectfully traverse the rejection of claim 13 based on Hofert in view of Morita and Abulhaj. Independent claim 13, as amended, includes all the limitations of independent claims 1 and 10. As discussed earlier in this paper, Morita in view of Abulhaj fails to disclose every limitation of independent claim 1 (please refer to sections I), and further, Hofert fails to disclose each and every limitation of claim 10 (please refer to section II). Therefore, a *prima facie* case of obviousness has not been established for independent claim 13, and claims 15, 17, 19 and 21-23 which depend from claim 13. Claims 13, 15, 17, 19, and 21-23 are therefore patentable over *Hofert* and *Morita*. Applicants respectfully request that the rejection of claims 13, 15, 17, 19, and 21-23 under 35 U.S.C. § 103(a) be withdrawn.

By this amendment, Applicants propose to cancel claims 14 and 16, thereby, mooted the rejection of these claims.

Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Hofert in view of Morita, and further in view of Duchon. The deficiencies of Hofert and Morita are discussed above.

With respect to Duchon, the Examiner alleges that "Duchon discloses that the contact surface (48) is concave..." (Id. at p. 10). Such teachings, even if present in Bajaj and Duchon, which Applicants do not concede, fail to cure the deficiencies of Hofert and Morita. Accordingly, claim 20 is patentable at least due to its dependence from independent claim 13.

### **CONCLUSION**

Applicants respectfully submit that claims 1, 3, 5, 7-13, 15, 17 and 19-23 are in condition for allowance.

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: May 11, 2009

*/Eric P. Raciti/*

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